

WHAT IS CLAIMED IS:

1                   1. A process for preparing a pharmaceutical composition comprising as  
2 an active ingredient a hygroscopic salt of valproic acid, comprising the step of intimately  
3 mixing (i) said hygroscopic salt; (ii) a carbomer and (iii) a non-hygroscopic additive to  
4 form a homogeneous mixture; wherein the amount of said carbomer and said non-  
5 hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to  
6 produce said mixture having the following property: when compressed into tablets, said  
7 tablets do not absorb more than 5% water by weight after being stored for 3 months at  
8 75% relative humidity.

1                   2. The process of claim 1, wherein said hygroscopic salt of valproic acid  
2 is sodium valproate.

1                   3. The process of claim 1, wherein the weight ratio of carbomer to the  
2 hygroscopic salt of valproic acid ranges from about 1:3 to about 1:100.

1                   4. The process of claim 1, wherein the weight ratio of carbomer to the  
2 hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

1                   5. The process of claim 1, wherein the weight ratio of non-hygroscopic  
2 additive to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:2.

1                   6. The process of claim 1, further comprising a step of adding at least  
2 one excipient to the mixture of said hygroscopic salt, said carbomer and said non-  
3 hygroscopic additive.

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1                   7. The process of claim 1, further comprising a step of compressing said  
2 non-hygroscopic composition into a solid dosage form.

1                   8. The process of claim 7, wherein said solid dosage form contains from  
2 about 50 to about 1200 mg of sodium valproate.

1                   9. The process of claim 8, wherein said solid dosage form contains from  
2 about 6 mg to about 400 mg of carbomer.

1                   10. The process of claim 9, wherein, said solid dosage form contains from  
2 about 90 mg to about 400 mg of non-hygroscopic additive.

1                   11. The process of claim 3, wherein said non-hygroscopic additive is  
2 selected from the group consisting of dibasic calcium phosphate anhydrous, calcium  
3 silicate, microcrystalline cellulose and mixtures thereof.

1                   12. The process of claim 3, wherein said non-hygroscopic additive is  
2 present in an amount such that the weight ratio of non-hygroscopic additive to the  
3 hygroscopic salt of valproic acid is in the range of from about 1:6 to 1:2.

1                   13. The process of claim 6, wherein said excipient is selected from the  
2 group consisting of lubricants, disintegrators, glidants, adsorbents, and mixtures thereof.

1                   14. The process of claim 13, wherein said lubricant is selected from the  
2 group consisting of stearic acid, a salt of stearic acid, talc, sodium lauryl sulfate, sodium  
3 stearyl fumarate and mixtures thereof.

1 15. The process of claim 14, wherein said lubricant is present in an  
2 amount of from about 0.25% to about 5% of the weight of the final composition.

1 16. The process of claim 13, wherein said disintegrator is selected from  
2 the group consisting of crosscarmelose sodium, sodium starch glycolate, starch,  
3 magnesium aluminum silicate, colloidal silicon dioxide, carboxymethyl cellulose,  
4 microcrystalline cellulose, and mixtures thereof.

1 17. The process of claim 16, wherein said disintegrator is present in an  
2 amount of from about 0.5% to about 25% of the weight of the final composition.

1 18. The process of claim 12, wherein said glidant is selected from the  
2 group consisting of colloidal silicon dioxide, talc and mixtures thereof.

1 19. The process of claim 18, wherein said glidant is present in an amount  
2 of from about 0.1 % to about 10% of the weight of the final composition.

1 20. The process of claim 13, wherein said adsorbent is selected from the  
2 group consisting of colloidal silicon dioxide, microcrystalline cellulose, calcium silicate  
3 and mixtures thereof.

1 21. The process of claim 20, wherein said adsorbent is present in an  
2 amount of from about 0.05% to about 42% of the weight of the final composition.

1 22. The process of claim 7, wherein said solid dosage form is selected  
2 from the group consisting of a tablet, a caplet, a pellet, a capsule, a tablet which  
3 disintegrates into granules, and a pill.

1 23. The process of claim 21, wherein the tablet is an enteric coated tablet.

1 24. The process of claim 21, wherein the tablet is coated with an anti-  
2 moisture barrier.

1 25. The process of claim 1, wherein said mixing is carried out in  
2 conditions of relative humidity of greater than 30%.

1 26. A non-hygroscopic oral pharmaceutical composition comprising a  
2 pharmaceutically effective amount of a hygroscopic salt of valproic acid, a carbomer, and  
3 a non-hygroscopic additive, wherein the amount of said carbomer and said non-  
4 hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to  
5 produce said composition having the following property: not absorbing more than 5% by  
6 weight water after being stored for 3 months at 75% relative humidity.

1 27. A non-hygroscopic oral pharmaceutical composition comprising a  
2 pharmaceutically effective amount of a hygroscopic salt of valproic acid, a carbomer, and  
3 a non-hygroscopic additive, wherein the amount of said carbomer and said non-  
4 hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to  
5 produce said composition having the following property: when compressed into tablets,  
6 said tablets do not absorb more than 5% by weight water after being stored for 3 months  
7 at 75% relative humidity.

1 28. The pharmaceutical composition of claim 27, wherein said  
2 hygroscopic salt of valproic acid is sodium valproate.

1                   29. The pharmaceutical composition of claim 27, wherein the weight  
2 ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about  
3 1:100.

1                   30. The pharmaceutical composition of claim 27, wherein the weight ratio  
2 of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

1                   31. The pharmaceutical composition of claim 29, wherein the non-  
2 hygroscopic additive is present in an amount such that the weight ratio of non-  
3 hygroscopic additive to the hygroscopic salt of valproic acid is in the range of from about  
4 1:6 to about 1:2.

1                   32. The pharmaceutical composition of claim 31, wherein said non-  
2 hygroscopic additive is present in an amount such that the weight ratio of the non-  
3 hygroscopic additive to the carbomer is in the range of from about 2:1 to about 35:1.

1                   33. The pharmaceutical composition of claim 27, further comprising at  
2 least one excipient.

1                   34. The pharmaceutical composition of claim 27, wherein the  
2 composition contains from about 50 to about 1200 mg of sodium valproate.

1                   35. The pharmaceutical composition of claim 34, wherein the  
2 composition contains from about 6 mg to about 400 mg of carbomer.

1                   36. The pharmaceutical composition of claim 35, wherein the  
2 composition contains from about 90 mg to about 400 mg of non-hygroscopic additive.

1 37. The pharmaceutical composition of claim 27, wherein said  
2 non-hygroscopic additive is selected from the group consisting of dibasic calcium  
3 phosphate anhydrous, calcium silicate, microcrystalline cellulose and mixtures thereof.

1 38. The pharmaceutical composition of claim 27, further comprising an  
2 excipient selected from the group consisting of lubricants, disintegrators, glidants,  
3 adsorbents, and mixtures thereof.

1 39. The pharmaceutical composition of claim 38 wherein said lubricant is  
2 selected from the group consisting of stearic acid, a salt of stearic acid, talc, sodium  
3 lauryl sulfate, sodium stearyl fumarate and mixtures thereof.

1 40. The pharmaceutical composition of claim 39, wherein said lubricant  
2 is present in an amount of from out 0.25% to about 5% of the weight of the final  
3 composition.

1 41. The pharmaceutical composition of claim 38, wherein said  
2 disintegrator is selected from the group consisting of crosscarmellose sodium, sodium  
3 starch glycolate, starch, magnesium aluminum silicate, colloidal silicon dioxide,  
4 carboxymethyl cellulose, microcrystalline cellulose, and mixtures thereof.

1 42. The pharmaceutical composition of claim 41, wherein said  
2 disintegrator is present in an amount of from about 0.5% to about 25% of the weight of  
3 the final composition.

1 43. The pharmaceutical composition of claim 38, wherein said glidant is  
2 selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof

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1 44. The pharmaceutical composition of claim 43, wherein said glidant is  
2 present in an amount of from about 0.1 % to about 10% of the weight of the final  
3 composition.

1 45. The pharmaceutical composition of claim 38, wherein said adsorbent  
2 is selected from the group consisting of colloidal silicon dioxide, microcrystalline  
3 cellulose, calcium silicate and mixtures thereof.

1 46. The pharmaceutical composition of claim 45, wherein said adsorbent  
2 is present in an amount of from about 0.05% to about 42% of the weight of the final  
3 composition.

1 47. The pharmaceutical composition of claim 27, wherein the  
2 non-hygroscopic oral pharmaceutical composition is a tablet, a caplet, a pellet, a capsule,  
3 a tablet which disintegrates into granules, and a pill.

1 48. The pharmaceutical composition of claim 47, wherein the tablet is an  
2 enteric coated tablet.

1 49. The pharmaceutical composition of claim 48, wherein the tablet is  
2 coated with an anti-moisture barrier.

1 50. The pharmaceutical composition of claim 27, wherein the  
2 non-hygroscopic oral pharmaceutical composition is a sustained release tablet wherein  
3 the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about  
4 1:6 to about 1:20.

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1                   51. The pharmaceutical composition of claim 50, wherein the  
2 non-hygroscopic oral pharmaceutical composition is a sustained release tablet.

1                   52. A method of treating a medical condition in a human patient, the  
2 method comprising the step of orally administering a non-hygroscopic pharmaceutical  
3 composition for release of a salt of valproic acid into the bloodstream at a physiologically  
4 effective level, wherein said composition comprises a pharmaceutically effective amount  
5 of a hygroscopic salt of valproic acid, a carrier, and a non-hygroscopic additive, and  
6 wherein the weight ratio of the carbomer to the hygroscopic salt of valproic acid is from  
7 about 1:3 to about 1:100 and the weight ratio of the non-hygroscopic additive to the  
8 hygroscopic salt of valproic acid is from about 1:6 to about 1:2 .

1                   53. The method of claim 52, wherein said medical condition is epilepsy.

1                   54. The method of claim 52, wherein said medical condition is a  
2 psychotic disorder.

1                   55. The method of claim 52, wherein said medical condition is a  
2 migraine headache.